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Registration Decision RD2016-20

Metofluthrin

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Registration Decision Statement[1] for Metofluthrin

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is granting full registration for the sale and use of SumiOne Technical Grade and OFF! Clip On Mosquito Repellent, containing the technical grade active ingredient metofluthrin, as a personal insect repellent.

This decision is consistent with the Proposed Registration Decision PRD2016-09, *Metofluthrin,* which contains a detailed evaluation of the information submitted in support of this registration. The evaluation found that, under the approved conditions of use, the products have value and do not present an unacceptable risk to human health or the environment. See Appendix I for a summary of comments received during the consultation process as well as the PMRA's response to these comments.

Other Information

The relevant test data on which the decision is based (as referenced in PRD2016-09, *Metofluthrin)* are available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa). For more information, please contact the PMRA's Pest Management Information Service by phone (1-800-267-6315) or by e-mail (pmra.infoserv@hc-sc.gc.ca).

Any person may file a notice of objection[2] regarding this registration decision within 60 days from the date of publication of this Registration Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the Pesticides and Pest Management portion of the Health Canada's website (Request a Reconsideration of Decision) or contact the PMRA's Pest Management Information Service.

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[1] "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act.*

[2] As per subsection 35(1) of the *Pest Control Products Act.*

Appendix I Comments and Responses

Comment

A comment was made in which concern was expressed over the PMRA's approach for the cancer risk assessment. In published PMRA documents for metofluthrin, it was concluded that although the proposed mode of action (phenobarbital-like) for rat liver tumour formation was deemed plausible, the overall weight of evidence to support it was deemed inadequate, and thus the PMRA considered the tumours relevant for the cancer risk assessment. Consequently, a linear low-dose extrapolation was utilized. The commenter was of the opinion that the body of available data, including expert opinions as well as recent studies and information in the published scientific literature, confirm the mode of action and thus the tumours are not relevant for human cancer risk assessment.

Response

The cited information/studies, which includes information that was not available at the time of the original toxicology review, has yet to be provided to the PMRA. Until such time as the PMRA receives this information, the approach to the cancer risk assessment will remain as is.